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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ANITA MARIA BURGHER, SUSAN MARIE KAUP, and CHARLES FRANCIS KUHLMAN

Appeal 2008-5439
Application 10/681,489
Technology Center 1600

Decided: January 06, 2009

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* GREEN.

Opinion Dissenting filed by *Administrative Patent Judge* GRIMES.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-3 and 5-7. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to an infant formula. Claim 1 is representative of the claims on appeal, and reads as follows:

1. An infant formula composition comprising 3.2 mg/L to 15.4 mg/L of CMP; 1.8 mg/L to 11.0 mg/L of UMP; 2.4 mg/L to 8.0 mg/L of GMP; 0.1 mg/L to 2.2 mg/L of IMP; and 2.5 mg/L to 13.2 mg/L of AMP.

The Examiner relies on the following reference:

Gil	US 5,066,500	Nov. 19, 1991

We affirm.

ISSUE

The Examiner finds that claims 1-3 and 5-7 are anticipated by Gil.

Appellants contend that Gil does not teach how much nucleotide is present in the infant formulas therein; and also contend that Gil does not anticipate the amount of GMP required by the claims on appeal.

Thus, the issue on Appeal is: Does Gil does teach how much nucleotide is present in the infant formulas therein; and does Gil anticipate the amount of GMP required by the claims on appeal?

FINDINGS OF FACT

FF1 The Examiner rejects claims 1-3 and 5-7 under 35 U.S.C. § 102(b) as being anticipated by Gil.

FF2 The Examiner finds that Gil

teaches an infant formula adding on a liquid basis, per dl:

- 0.28-2.62 mg of uridine phosphate,
- 0.04- 0.5 mg of guanosine phosphate,
- 0.64-1.43 mg of adenosine phosphate,
- 0.53- 1.53 [mg] of cytidine phosphate and

- 0-0.29 mg of inosine phosphate (col. 5, line 66-col 6 line 5; and claim 12).

(Ans. 3-4 (*see* Gil, col. 5, l. 67-col. 6, l. 5; *see also* col. 10, Table I).)

FF3 The Examiner finds further that Gil teaches that "the terms uridine phosphate, guanosine phosphate, etc [are] intended to refer collectively to mono, di and/or tri phosphates but that for reasons known to those skilled in the art, the 5'-monophosphates are preferred." (Ans. 3.)

FF4 According to the Examiner, Gil teaches that the "supplementation of nucleotides to infant formulas of Gil [ ] gives a better physiological fatty acid tissue membrane to newborns, an improved cell immunity and better intestinal repair to those patients with intestinal diseases." (*Id.* at 4.)

FF5 Gil discloses "infant formulas and clinical nutrition products enriched with nucleosides, nucleotides or mixes of these two classes of compounds." (Gil, col. 4, ll. 66-68.)

FF6 Gil teaches that "[i]n general, infant formulas tend to have a composition qualitatively and quantitatively as similar as possible to human milk." (Col. 1, ll. 62-64.)

FF7 Specifically, Gil teaches:

> [O]ne embodiment of the present invention provides for a nutritionally balanced diet formulation which comprises a source of amino nitrogen, carbohydrates, edible fats, minerals, vitamins and a nucleoside/nucleotide composition containing at least one of:
> a) uridine, uridine phosphate or a mixture thereof;
> b) guanosine, guanosine phosphate or a mixture thereof;
> c) adenosine, adenosine phosphate or a mixture thereof;
> d) cytidine, cytidine phosphate or a mixture thereof; or
> e) inosine, inosine phosphate or a mixture thereof.

> Thus, the formulation must contain at least one of the fifteen different possible components in an amount (based on 100 grams of dry product) equal to 1 mg.

(Col. 5, ll. 21-34).

FF8 Gil teaches that the "content of nucleosides and/or nucleotides in the infant formulas of the present invention are in the range of those for human milk. An exemplary nucleoside and/or nucleotide mixture for infant formulas not containing cow's milk, according to the invention, is shown in Table I [*i.e.*, the amount found by the Examiner in FF2]." (Col. 8, l. 65-col. 9, l. 2).

FF9 Thus, Gil teaches that the formula may contain only nucleoside, only nucleotide, or a mixture thereof. Therefore, Gil discloses infant formulas (Cols. 9-10, ll. 7-18) comprising (per deciliter) a mixture of

0.28-2.62 mg of uridine phosphate,

0.04-0.5 mg of guanosine phosphate,

0.64-1.43 mg of adenosine phosphate,

0.53-1.53 mg of cytidine phosphate and

0-0.29 mg of inosine phosphate

FF10 A comparison of the amount of nucleotide required by the claimed formula to the formula of Gil is set forth below.

nucleotide	Claim 1 in mg/dl[1]	Claim 2 in mg/dl	Gil in mg/dl From Table I
CMP	0.32-1.54	0.42-1.16	0.53-1.53
UMP	0.18-1.10	0.24-0.83	0.28-2.62

[1] The claimed amounts are in "mg/L". These values were converted to deciliters ("dl") by dividing by 10.

GMP	0.24-0.8	0.24-0.6	0.04-0.5
IMP	0.01-0.22	0.01-0.17	0.00-0.29
AMP	0.25-1.32	0.33-0.99	0.64-1.43

FF11 Thus the claimed ranges do not substantially deviate from the ranges disclosed by Gil, e.g., , overlapping at least one end of the range and very close to the numerical value disclosed by Gil for the other end of the range.

PRINCIPLES OF LAW

"It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). In addition, "[a]nticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure." *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).

Anticipation has been found even when a prior art range "does not exactly correspond to [the] claimed range," but the prior art range "does not significantly deviate from, [the] claimed ranges." *See Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005) (court found that a claimed range of 0.025 to 5% did not significantly deviate from a prior art range of 0.01 to 20%). We recognize that in *Perricone*, the prior art range "entirely encompasse[d]" the claimed ranges. But the court cited *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999) for the proposition that "[w]hen a patent claims a chemical composition in terms of

ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim." *Perricone*, 432 F.3d at 1377. Thus, we interpret the court's holding in *Perricone* as resting on the amount of deviation between the prior art range and the claimed range, and not specifically requiring that the prior art range completely encompass the claimed range. *See, e.g., Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) (finding that a disclosed temperature range of 100 to 500°C did not anticipate the claimed temperature range of 330 to 450°C, even though the prior art range encompassed the claimed range, because "[g]iven the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.").

ANALYSIS

Appellants argue that Gil "teaches the supplementation of infant formula with nucleosides and/or nucleotides, specifically 0.28-2.8 mg/dl uridine and/or uridine phosphate, 0.04-0.50 mg/dl guanosine and/or guanosine phosphate, 0.64-1.43 mg/dl adenosine and/or adenosine phosphate, 0.53-1.53 mg/dl cytidine and/or cytidine phosphate, and 0-0.29 mg/dl inosine and/or inosine phosphate." (App. Br. 4-5). According to Appellants, Gil does not teach an infant formula containing the claimed ranges of nucleotides, but instead in Gil, "nucleosides and nucleotides are lumped together without clearly stating how much of each is included." (*Id.* at 5.) Appellants assert further that Gil does "not state that any minimum

amount of nucleotide is required," and in fact teaches that "nucleosides are more effective that nucleotides." (*Id.*)

Moreover, Appellants assert, Gil does state the "concentrations of CMP, GMP, AMP, UMP and IMP in human milk, including a range of 0.04-0.21 mg/dl GMP, and further states that the patented invention uses nucleosides/nucleotides in the range that they are present in human milk." (*Id.*) Appellants argue that teaching of Gil would require the formula of Gil to contain 0.04 to 0.21 mg/dl GMP, whereas the formula of claim 1 requires 0.24 to 0.80 mg/dl (*i.e.*, 2.4 mg/L to 8.0 mg/L), and thus Gil suggests using less GMP than is required by the formula of claim 1 (*id.*).

Appellants' arguments are not convincing. Gil makes clear that when the reference is referring to nucleosides and nucleotides, the formula or dietary supplement can contain all nucleosides, all nucleotides, or a mixture of both (FF8). Thus Gil anticipates formulas containing only nucleotides as required by the instant claims (FF9).

Moreover, while Gil may have a preferred range of 0.04-0.21 mg/dl of GMP, the reference clearly teaches a range of 0.04-0.5 mg/dl of GMP (FF9), which is not substantially different from the range required in claim 1 of 0.24-0.8 mg/dl (2.4 mg/L to 8.0 mg/L) GMP (FF10-11), and Appellants do not point out why the overlapping range disclosed by Gil would not anticipate the range of GMP required by claim 1.

We thus affirm the rejection as to claim 1. As Appellants do not argue claims 5 and 6 separately from claim 1, the rejection is also affirmed as to those claims. 37 C.F.R. § 41.37(c)(1)(vii).

As to claims 2 and 3, Appellants argue that the ranges of GMP required by the claims are even farther from the preferred range of Gil of 0.04-0.21 mg/dl (App. Br. 6). But, as discussed above, while that range may be preferred by Gil, Gil clearly teaches a range of 0.04-0.5 mg/dl of GMP (FF9), and Appellants do not present any argument or reasoning as to why that broader range would not anticipate the ranges required by claims 2 and 3.

As to claim 7, Appellants argue that the claim requires feeding the formula of claim 1 to a preterm infant, and as Gil does not teach the formula of claim 1, the reference cannot teach feeding the formula of claim 1 to infants (App. Br. 6). However, we have found that Gil anticipates the formula of claim 1, and the reference also anticipates feeding the formula to preterm infants (Answer 4; Gil, col. 13, ll. 53-57). The rejection is therefore also affirmed as to claim 7.

CONCLUSIONS OF LAW

Thus, we find that Gil does teach how much nucleotide is present in the infant formulas therein; and Gil also anticipates the amount of GMP required by the claims on appeal.

The rejection of claims 1-3 and 5-7 under 35 U.S.C. § 102(b) is therefore affirmed.

TIME LIMITS

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

GRIMES, *Administrative Patent Judge*, dissenting.

I respectfully dissent. I agree with my colleagues that Gil discloses compositions that have the same ingredients, in similar amounts, to those of the claims on appeal. In my view, however, the facts of this case do not support a finding of anticipation.

The majority relies on *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005), concluding that the claimed ranges in this case, as in *Perricone*, do not deviate significantly from the ranges disclosed in the prior art. *Ante* at 5-6. The claims in *Perricone* were directed to methods of treating skin using a composition containing fatty acid esters of ascorbic acid. 432 F.3d at 1373. The claims recited different amounts of fatty acid esters, ranging "from an 'effective' amount in claim 1 to particular specific ranges in other claims (e.g., 'up to 10% by weight,' '063 patent, claim 2; 'from about 0.025% to about 5% by weight,' '063 patent, claim 3; 'from about 0.025% to about 10% by weight,' '063 patent, claim 22)." *Id.* at 1377.

The prior art reference in *Perricone* disclosed topical application of a composition comprising a fatty acid ester of ascorbic acid in an amount of 0.01 to 20% by weight. *See id.* The court held that the prior art range "entirely encompasses, and does not significantly deviate from, [the] claimed ranges," and that the prior art compositions met the limitations of the claims on appeal. *Id.*

Perricone must be contrasted with *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006), which was decided only three months later. The claims in *Atofina* were directed to a method of making difluoro-methane: "Claim 1 requires that the process be conducted in the presence of 0.1 to 5 moles of oxygen per 100 moles of methylene chloride, at a temperature of between 330 and 450 °C.'" 441 F.3d at 993.

The prior art reference in *Atofina* disclosed a similar process carried out at a temperature between 100° C and 500° C and using 0.001 to 1.0% oxygen to methylene chloride (rather than 0.1 to 5% as claimed). *Id.* at 994, 999. The *Atofina* court held that

> the prior art . . . discloses a temperature range of 100 to 500 °C which is broader than and fully encompasses the specific temperature range claimed . . . of 330 to 450 °C. Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation.

Id. at 999.

That is, *Perricone* held that a prior art range of 0.01 to 20% anticipated, among others, a claimed range of 0.025% to about 5% because it fully encompassed the claimed range and did not deviate from it significantly. The claimed range in *Perricone* made up about 25% of the prior art range.[2] And *Atofina* held that a prior art range of 100 to 500° C that fully encompassed a claimed range of 330 to 450° C did not anticipate because there was a "considerable difference" between the two ranges. The claimed range in *Atofina* made up 30% of the prior art range.[3]

The *Atofina* court cited *Perricone* (*see* 441 F.3d at 999) but did not explain why the facts of the two cases resulted in different outcomes. The cases provide no general principle, for example, for determining whether Gil's disclosure of a composition comprising 0 to 0.29 mg/dl of IMP anticipates the limitation of claim 1 requiring 0.01 to 0.22 mg/dl of IMP.

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[2] (5 – 0.025)/(20 – 0.01) x 100 = 24.9%.
[3] 120/400 x 100 = 30%.

Reconciling *Perricone* and *Atofina* can be left for another day, however, since the other ranges disclosed by Gil do not fully encompass the ranges recited in the claims.

In my view, that fact makes this case more similar to *Atofina* than to *Perricone*. Besides addressing the difference in temperature ranges, the *Atofina* court also addressed the difference between the prior art's disclosure of a 0.001 to 1.0% ratio of oxygen to methylene chloride, compared to the claimed range of 0.1 to 5%. 441 F.3d at 1000. The court held that the prior art range did not anticipate: "Once again, although there is a slight overlap, no reasonable fact finder could determine that this overlap describes the entire claimed range with sufficient specificity to anticipate this limitation of the claim." *Id.*

Here, as discussed in detail by the majority, most of the ranges disclosed by Gil overlap the ranges recited in the claims:[4]

- for UMP, claim 1 recites 0.18-1.10 mg/dl, while Gil discloses 0.28-2.62 mg/dl;
- for GMP, claim 1 recites 0.24-0.8 mg/dl, while Gil discloses 0.04-0.5 mg/dl;
- for AMP, claim 1 recites 0.25-1.32 mg/dl, while Gil discloses 0.64-1.43 mg/dl.

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[4] Gil's CMP range of 0.53-1.53 mg/dl is entirely within claim 1's range of 0.32-1.54 mg/dl, which the *Atofina* court implied would suffice to anticipate that limitation. *See* 441 F.3d at 999 ("*Titanium Metals* stands for the proposition that an earlier species reference anticipates a later genus claim.").

The claimed and prior art ranges here are closer than those in *Atofina*, where the claimed composition could have a ratio of oxygen to methylene chloride five times higher than what was disclosed in the prior art. *See* 441 F.3d at 1000. Nonetheless, the critical question under *Atofina*, as I understand it, is whether the prior art range "describes the entire claimed range with sufficient specificity to anticipate this limitation." 441 F.3d at 999.

In this case, the prior art composition can include 2.5 times as much UMP as allowed by claim 1 (2.62 compared to 1.10 mg/dl), while claim 1 can include 1.5 times as much GMP (0.8 compared to 0.5 mg/dl) and less than half the AMP (0.25 compared to 0.64 mg/dl) as the prior art composition.

I cannot say that the ranges disclosed in Gil describe each of the ranges recited in claim 1 with sufficient specificity to anticipate them. "Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." *Gechter v. Davidson*, 116 F.3d 1454, 1457 (Fed. Cir. 1997). In my view, therefore, *Atofina* requires reversal of the rejection on appeal.

dm

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